

NASAL CANNULA**INVENTOR: Norman Cardoso****CROSS REFERENCE TO RELATED APPLICATIONS**

10 This application claims the benefit of U.S. Provisional Application Serial No. 60/409,771 entitled "IMPROVED NASAL OXYGEN CANNULA," and filed on September 10, 2002, and is a continuation-in-part of and claims the benefit of U.S. Patent Application Serial No. 09/994,571, filed on November 11, 2001 entitled "NASAL OXYGEN CANNULA WITH SUPPLY TUBE MANAGEMENT," the contents of
15 which are incorporated herein by reference.

BACKGROUND OF THE INVENTION**1. Technical Field:**

20 The present invention relates generally to nasal oxygen cannula technology, and in particular, to an apparatus and method for stabilizing and anchoring nasal oxygen cannulas in a secure and comfortable manner.

2. Description of the Related Art:

25 Nasal oxygen cannulas are utilized to deliver oxygen directly to nasal airways in order to infuse oxygen into the inspirational airflow of patients in need of such therapy. Typically, these systems include a relatively large bore plastic supply tube as a conduit for providing gas flow from a pressurized oxygen source to proximal ends of a pair of plastic oxygen delivery tubes having relatively smaller bores. In a typical nasal cannula configuration, the distal ends of the delivery tubes enter into opposite ends of a short, expanded piece of plastic tubing, referred to herein as an oxygen delivery barrel. In the
30 foregoing manner, the oxygen delivery barrel joins the two oxygen delivery tubes in a loop configuration. The barrel is typically cylindrical in shape, formed of a short length

5 of enlarged plastic tubing provided with smaller diameter, stub-like extensions referred to herein as cannula delivery ports. The ports are open at their distal ends and are positioned in circumferential alignment upon the barrel and transverse to the longitudinal axis of the barrel. The cannula delivery ports are positioned so that the distance therebetween approximates an average distance between the nares in which they will be
10 positioned. The terms "cannula," "nasal cannula," and "nasal oxygen cannula" are utilized throughout this specification and within the claims interchangeably, and refer, collectively and individually to an apparatus or device comprised of various tubing and associated retention/anchoring structure for delivery oxygen or other respiratory gases or mixtures of respiratory gases to a patient through the patient's external nasal passages.

15 An example prior art nasal oxygen cannula design is depicted in **Figure 1**. Starting at the distal end, as shown in **Figure 1**, the nasal cannula includes a tube coupler **62** designed to mate to an oxygen supply tube fitting (not depicted) on its proximal end. The distal end of tube coupler **62** joins with a single lumen supply tube **64** that branches into a pair of oxygen delivery tubes **68** which in turn terminate at an oxygen supply barrel
20 **63**. With the bores of the oxygen supply tube, oxygen delivery tubes, oxygen supply barrel and delivery ports in mutual fluid communication, oxygen is supplied from a pressurized oxygen source to the proximal end of the single lumen supply tube **64** from which it flows into delivery tubes **68** and into the patients nasal passages through a pair of oxygen ports **65** protruding from delivery barrel **63**. The source oxygen supply is
25 typically pressurized with the patient's inspirational airflow assisting the oxygen intake.

To ensure adequate and uninterrupted oxygen delivery, nasal cannulas must be securely positioned such that the delivery ports on the oxygen supply barrel are maintained in secure alignment with a patient's nostrils. Conventional catheter/cannulas have largely depended upon the use of the pair of oxygen delivery tubes, such as those
30 depicted in **Figure 1**, to stabilize the barrel's position under the nose and thereby maintain the cannula delivery ports within the patient's nostrils. By looping each of two delivery tubes over the top of each ear, a portion of the tube becomes trapped in the sulcus area between the ear and the skin of the head. The traction provided by trapping the tubes within the sulcus, prevents free movement of the delivery tubes and thus
35 provides stabilization of the oxygen delivery barrel under a patient's nose.

5 The delivery tube ear loop design of the apparatus shown in **Figure 1** achieves limited cannula stabilization that resists displacement of the delivery ports upon movement of the patient's head. However, there are also many disadvantages and limitations related to utilizing this conventional apparatus and method. For example, patients tend to move their heads during sleep, resulting in an associated movement of the pair of oxygen delivery tubes looped behind the ears. Movement of these tubes often causes irritation, abrasion and pain arising from friction at the skin folds comprising the sulcus between the ear and lateral head area. Responsive to such irritation and pain, patients often "shake off" the catheter/cannula resulting in considerable sleep interruption and, more importantly, interruption of the patient's necessary oxygen supply.

15 The above-described cannula positioning/retention problems are, to some extent, addressed by U.S. Patent No. 6,093,169 (the '169 patent). To improve retention of the cannula delivery ports within the nostrils, the '169 patent discloses a detachable retainer that is positioned along the ridge pole of the nose. The ridge pole retainer is generally configured as an L-shaped strut having a long "leg" and a short "leg." The long leg of the strut is configured and adapted to conform to and lie upon the ridge pole of the nose from the root of the nose to an area proximate to the tip of the nose. The strut is comprised of a flexible material such as a plastic or fabric covered/padded metal framework that may be secured to the ridge pole of the nose with a suitable adhesive means. The short leg of the strut lies in an angular relationship with the long leg such that it may be positioned under the nose, generally in line with the nasal septum.

25 The short leg also includes, in certain preferred embodiments, a curved portion that is especially adapted and configured to pass around and securely retain an oxygen delivery barrel. The barrel is thus held and secured in a position and orientation that assures that cannula delivery ports protruding transversely therefrom remain secured within a patient's nostrils.

30 As described above, the device disclosed by the '169 patent is advantageously comprised of a springy plastic or springy metal backbone demonstrating high elastic memory within operational limits. The contour and elasticity of the device provide a traction force to the nose when the device is secured along the ridge pole of a patient's

5 nose. The traction force of the device, so applied and secured, tends to pull the tip of the
wearer's nose both upward and inward. More specifically, as the long arm of the retainer
is urged upward towards the root of the nose, the short leg flange portion pulls the tip of
the nose upward and inward towards the forehead. The pulling upward and inward of the
tip of the nose tends to shorten and increase the diameter of the external nasal airway. As
10 a result, the external nasal bore, widened and shortened, provides decreased airway
resistance, allowing greater inspiration and more efficient oxygen delivery to the patient,
while simultaneously providing improved stabilization and retention of the oxygen
delivery barrel under the patient's nose.

Although the device described by the '169 patent provides increased cannula
15 stabilization, it is still utilized with the above-described ear loops in order to further
stabilize the device. Thus, although greater stability is provided by the cannula support
device described therein, a patient remains susceptible to irritation, abrasion and resultant
"throw off" associated with such loops.

What is needed is a nasal cannula device and method of utilizing same, which
20 provides the increased stabilization and increased airway efficiency demonstrated by the
'169 patent, while, at the same time, eliminating the use of ear loops and the irritations
and abrasions associated with the use thereof. The present invention addresses such a
need.

SUMMARY OF THE INVENTION

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An improved nasal cannula and cannula support structure are disclosed herein. In a preferred embodiment, an integrated nasal cannula and cannula support device comprise a semi-rigid mono-lumen cannula design comprising a generally L-shaped mono-lumen strut terminating at its distal end with an oxygen supply barrel. In an alternate embodiment of the present invention designed for use with conventional delivery tube pair cannula designs, a nasal cannula support device includes a ridge pole retainer comprising a generally L-shaped strut having a long leg and a short leg. The cannula support is anchored to the wearer's nose and/or forehead such that the cannula delivery tubes and supply barrel are maintained in fixed alignment regardless of the wearer's head motion.

All objects, features, and advantages of the present invention will become apparent in the following detailed written description.

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BRIEF DESCRIPTION OF THE DRAWINGS

The novel features believed characteristic of the invention are set forth in the appended claims. The invention itself however, as well as a preferred mode of use, further objects and advantages thereof, will best be understood by reference to the following detailed description of an illustrative embodiment when read in conjunction
10 with the accompanying drawings, wherein:

Figures 1 depicts a conventional dual-lumen nasal cannula apparatus;

Figures 2A-2C illustrate a mono-lumen nasal cannula in accordance with one embodiment of the present invention;

Figures 3A and 3B illustrate alternate perspective views of a nasal cannula support apparatus in accordance with an alternate embodiment of the present invention;
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Figures 4A and 4B depict alternate perspective views of a combined nasal cannula and support apparatus in accordance with an alternate embodiment of the present invention;

Figures 5A and 5B illustrate side and front profile views of a nasal cannula and support apparatus as deployed on a patient in accordance with the embodiment depicted
20 in **Figures 3A-3B** and **Figures 4A-4B**; and

Figure 6 depicts a nasal cannula support and tube biasing apparatus in accordance with an alternate embodiment of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The present invention is described in a preferred embodiment in the following description with reference to the figures. While this invention is described in terms of the best mode for achieving this invention's objectives, it will be appreciated by those skilled in the art that variations may be accomplished in view of these teachings without deviating from the spirit or scope of the present invention.

The present invention is directed to a nasal cannula support device that provides improved stabilization of the cannula apparatus and associated tubing while eliminating the need for ear loop retention and stabilization. Each of the embodiments of the present invention provide stabilization of the oxygen barrel within a patient's nostrils while managing or eliminating the need for a pair of side-mounted oxygen delivery tubes feeding the supply barrel. Conventional methods for securing the oxygen delivery tubes result in the tubes rubbing and chafing the sulcus area of skin behind a patient's ears, causing significant patient discomfort and increased potential for intentional or unintentional removal of the apparatus by the patient. The present invention reduces the frequency of cannula loss/displacement, decreases the need for replacement of same by nursing staff, and increases patient comfort.

In a preferred embodiment, an integrated nasal cannula and cannula support device comprise a semi-rigid mono-lumen cannula design comprising a generally L-shaped mono-lumen strut terminating at its distal end with an oxygen supply barrel. In an alternate embodiment of the present invention designed for use with conventional delivery tube pair cannula designs, a nasal cannula support device includes a ridge pole retainer comprising a generally L-shaped strut having a long leg and a short leg. The cannula support is anchored to the wearer's nose and/or forehead such that the cannula delivery tubes and supply barrel are maintained in fixed alignment regardless of the wearer's head motion.

With reference now to the figures, wherein like reference numerals refer to like and corresponding parts throughout, and in particular with reference to **Figures 2A-2C** there is illustrated a mono-lumen nasal cannula **10** in accordance with a preferred embodiment of the present invention. Nasal cannula **10** comprises a mono-lumen tube

5 that is contoured from the forehead down upon the ridge pole of the nose. The material used to construct the tubular portion or nasal cannula 10 is preferably substantially rigid. At its proximal end 4, nasal cannula 10 is coupled to an oxygen supply source (not depicted) such as a flexible feed tube from an oxygen tank or wall fitting. As further depicted in **Figures 2A** and **2C**, the mono-lumen body of nasal cannula 10 is formed as a
10 generally L-shaped strut having a short leg or flange 6 angularly connected in a contiguously bending manner to a long leg 2 that rests in generally flush contact with the ridge pole of the patient's nose. In the depicted embodiment, long leg 2 includes an intermediate bend between proximal end 4 and the junction with short leg 6 to accommodate the corresponding contour of a patient's face at the junction between the
15 forehead and nose bridge.

Short leg 6 is contoured to extend over the tip of a patient's nose and terminates at its distal end under the nasal septum with a nosepiece 8. As shown in **Figures 2A** and **2C**, nosepiece 8 preferably comprises an enlarged area (compared with the incoming short leg tube diameter) hollow body, and in the depicted embodiment comprise a barrel-
20 shaped body having a septum bearing surface 9 from which intra-nasal ports 5 extend in general alignment with the patient's nares.

The cannula design depicted in **Figures 2A-2C** is a significant departure from conventional designs in which the oxygen supply barrel is fed by two oxygen delivery tubes mounted at each end of the barrel (see **Figure 1**). Specifically, the present
25 nosepiece 8 is sealed at its tranverse ends and is fed by short leg 6, comprising a single, centrally disposed lumen tube. As shown in the illustrated embodiment, the single short leg feed lumen 6 is preferably conjoined to oxygen delivery nosepiece 8 at an entry port at its approximate midpoint between intra-nasal cannula delivery ports 5. In joining the mono-lumen tubing into nosepiece 8, the angle between the tubing comprising short leg 6
30 and cannula delivery ports 5 is selected such that ports 5 are positioned in relative parallel alignment with the nasal passages of a patient and enter the top of the "V" formed by the meeting of the septum with the lateral nasal walls and then travel slightly inward along this sulcus.

5 Referring to **Figure 2C**, a slight traction is applied to nasal cannula **10** from a strap or headband **12** that is utilized to secure the proximal end **4** of nasal cannula **10** against a patient's forehead while cannula delivery ports **5** securely anchored within the nares. This traction force is applied against the septum in an inward direction (i.e. from the tip of the nose toward the forehead), resulting in a shortening of the nasal airway and
10 a slight increase in bore of the nares, facilitating airflow therethrough. Strapping the proximal end **4** of nasal cannula **10** at approximately the mid-forehead level facilitates stabilization of the entire device along the axis of the nose as well as maintaining this portion of the device in relative flush contact against the upper ridge of the nose **15**.

In a preferred embodiment, forehead band **12** consists of a double layer of fabric
15 material. A relatively narrow channel or pocket (not depicted), just wide enough to enable passage of the proximal end of the tubular strut member of nasal cannula **10** traverses this band at a right angle. The single-lumen tubular strut passes up the length of the nose onto the forehead and then through the pocket. The pocket may be internally coated with adhesive or an attachment tab or other device may be fitted to the tubing to
20 secure it to the headband at a particular level. Once the entire cannula device has been fitted distally with cannula ports **5** inserted into the nares, forehead band **12** is slid slightly toward the top of the patient's head until the desired traction is provided.

Further stabilization of nasal cannula **10** to the patient's nose is provided by the pre-manufactured inclusion or post-manufacture application of a nasal shield stabilizer **14**
25 having a central portion **11** secured by adhesion or manufacturing processing, such as plastic injection molding, to the long leg member **2** and furthermore having lateral wings **16** that are secured to each side of the patient's nose. As shown in **Figure 2C**, nasal shield stabilizer **14** is preferably disposed underneath long leg **2** between the top surface of the ridge pole of the nose and the opposing bottom surface of long leg member **2** of the
30 single lumen strut. Nasal cannula **10** may not need to be reinforced if it is molded together with the underlying nasal shield stabilizer **14**. The material composition of nasal shield stabilizer **14** preferably provides a semi-rigid support structure that is molded to long leg member **2** to eliminate or reduce the need to reinforce the single lumen tube structure of nasal cannula **10**. For embodiments in which nasal shield stabilizer **14** is not
35 molded together with the lumen tube, various types of materials providing additional

5 strength and rigidity such as springy malleable brass shim stock, which is preferably covered or padded, may be used with a strip of medical application adhesive tape used to bond the tubing to the stabilizer 14.

10 In the preferred embodiment shown in **Figure 2B**, nasal shield stabilizer 14 narrows from its front edge 19, which is fitted near toward the tip of the nose, to its rear edge 21 fitted near the base of the nose. If, instead of manufacturing nasal shield stabilizer 14 and the mono-lumen strut member comprising long leg 2 and short leg 6 as an integrally plastic injection or extruded molding member, the tube/strut member and nasal shield are manufactured as separate pieces, nasal shield stabilizer 14 preferably includes an adhesive surface layer or strip along its central support strip region 11 at
15 which the stabilizer can be adhesively coupled to the tubular strut member. An adhesive layer may be similarly included on the opposing surface of the tubular strut member to provide adequate adhesion.

The lateral wings 16 are preferably constructed either of plastic (if fabricated as an integral unit with cannula 10) or of a thin springy brass shim stock or other deformable
20 material having elastic memory such that although the entire nasal shield stabilizer is manufactured as an originally flat member, the shield may be rolled or otherwise pressed about an internally situated molding object, such as a tubular mold, resulting in lateral wings 16 drooping with sufficient springiness to lightly grasp the body of the nose between the wings. The disposition of lateral wings 16 on both side of the nose provides
25 lateral stability for nasal cannula 10.

Referring to **Figures 3-5**, there is illustrated a nasal cannula support apparatus for securing a conventional dual oxygen delivery tube cannula design in accordance with an alternate embodiment of the present invention. Specifically, a nasal cannula support apparatus 30 includes a longitudinal support brace 32, which similar to the tubular strut
30 member depicted in **Figures 2A** and **2C**, is formed as an L-shaped strut have a long leg 31 upon which various head and nose anchoring features are mounted and a short leg 33 flanging therefrom.

At the distal end of short leg 33, a curved clip portion 34 securely retains an oxygen barrel 44 under the nose and cannula delivery ports 46 within the nostrils.

5 Cannula delivery ports **46** are in fluid communication with the oxygen delivery barrel **44** and a pair of oxygen delivery tubes **43**. An oxygen supply source (not depicted) provides pressurized oxygen to an oxygen supply tube (not depicted) which, in turn, communicates at a distal end thereof with proximal ends of the delivery tubes **43**.

10 In the depicted embodiment, longitudinal support brace **32** is secured to the nose by means of a cross member **38** having eyeglass-like nasal pads **39** adjustable to rest on each side of the root of the nose. In an alternative embodiment, adhesive tape, adhesive backings, or precision contouring of support brace to conform to the contour of the nose may be used in place of nasal cross member **38** and pads **39** to secure support brace **32** to the nose. As shown in **Figures 5A-5B**, longitudinal support brace **32** preferably extends
15 superiorly beyond the root of the nose to the mid to upper region of the patient's forehead.

In accordance with the depicted embodiment, cannula support apparatus **30** further includes a forehead cross brace **35** for laterally securing longitudinal support brace **32** at a point approximately halfway up the patient's forehead. Forehead cross
20 brace **35** is preferably constructed as a plastic injection molded piece, or in the alternative, may be made of springy brass shim stock, a strip of adhesive tape or an elastic band. If an elastic headband is used in place of the depicted forehead cross brace **35**, the object attachment preferably has sufficient elastic pull to yield a slight upward traction on the clip **34**, thus maintaining delivery ports **46** securely anchored within the
25 nares. In a preferred embodiment, the lever action imparted by the headband or cross brace **35** on longitudinal support brace **32** is sufficient to achieve a slight shortening and flaring of the nares, resulting in an increased airway and decreased airflow resistance through the nares.

As further depicted in **Figures 3-5**, cannula support apparatus **30** further includes
30 a tubing support cross brace **36** transversely attached to longitudinal support brace **32** below cross brace **38**. Tubing support cross brace **36** may be formed as an integral unit with cannula support apparatus **30** using plastic injection molding or may be a separately formed plastic or metallic member soldered or otherwise coupled thereto. As shown in the depicted embodiment, tubing support cross brace **36** includes open-loop clips **37** on

5 each opposing side of longitudinal support brace 32 for retaining the respective oxygen supply tubes 43 on either side of the brace. Referring in particular to **Figures 4A, 4B, 5A and 5B**, the apparatus is deployed as follows. The double branching cannula tubing 43 is coupled to the opposing ends of oxygen delivery barrel 44 which is clipped into loop clip 34 with cannula delivery ports 46 pointing toward the patient's forehead. In this manner, and as depicted in **Figure 5B**, ports 46 enter the right and left nostrils with loop clip 34 disposed between and just external to the end of the septum. The oxygen delivery tubes 43 leading away from each end of delivery barrel 44 are led and secured to the opposing sides of the patient's nose by inserting or pushing the tubes 43 into clips 37. From clips 37, the oxygen delivery tubes 43 are led upward and backward in a path centrally and longitudinally aligned with longitudinal support brace 32 and at approximately 1 inch below the boss of the patient's forehead, the tubes are wrapped together upon support brace 32 with tape or other suitable adhesion means.

In addition to addressing the problems relating to securing a cannula to a patient's nares and patient discomfort resulting from the traditional behind-the-ears anchoring of nasal cannulae, the present invention further addresses problems relating to the tendency of the oxygen delivery tubes to become snagged in bedclothes or sheets. With reference to **Figure 6**, there is depicted an apparatus for managing the cannula oxygen delivery tubing including a means and method by which the nasal cannula can be floated away from the patient to assure the patient's comfort and reduce the chance of snagging and/or removing the cannula. Specifically, **Figure 6** illustrates a patient 55 wearing a cannula support apparatus 50, which may be designed in accordance with the mono-lumen design shown in **Figures 2A-2C** or in accordance with the double branching support shown in **Figures 3-5**. An oxygen supply tube 51 (connected to mono-lumen cannula 10 for the embodiment shown in **Figures 2A-2C** or dual delivery tubes 43 for the embodiment in **Figures 3-5**), is led upward from the patient's forehead and up and through a smooth ring 48 which act as a balance point. Ring 48 may be support by a line from a mobile intravenous stand 52 or similar support. The length of cannula tubing 51 is maintained in slight tension by a biasing means. In the depicted embodiment, the biasing means comprises a counterweight 49 coupled to the cannula tubing 51 on the other side of ring 48. In the configuration illustrated in **Figure 6**, the ring 48 and counterweight 49 provide

5 a sufficient biasing force on cannula tubing **51** to float the tubing above and away from the patient and is a valuable adjunct in maintaining the patient's comfort. In this manner, the present invention reduces or eliminates excess oxygen tubing, thus reducing the susceptibility of the cannula to be unintentionally avulsed. The length of cannula tubing **51** between the balance point on ring **48** (or a suitable alternative balance point such as
10 the flat edge of a headboard) and counterweight **49** is preferably selected to allow for the maximum distance the patient's head will travel as he adjusts himself in bed and of a sufficient length to enable the patient to sit up in bed.

While this invention has been described in terms of several embodiments, it is contemplated that alterations, permutations, and equivalents thereof will become apparent
15 to one of ordinary skill in the art upon reading this specification in view of the drawings supplied herewith. It is therefore intended that the invention and any claims related thereto include all such alterations, permutations, and equivalents that are encompassed by the spirit and scope of this invention.